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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------------|
| 08/932,227 | 09/17/1997 | ERIC T. FOSSEL | S1509.70029US00 | 5092 |
| 23628 7590 04/23/2008 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 | | | EXAMINER MULLIS, JEFFREY C | |
| | | | ART UNIT 1796 | PAPER NUMBER |
| | | | MAIL DATE 04/23/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 08/932,227 | Applicant(s) FOSSEL, ERIC T. | |
| | Examiner Jeffrey C. Mullis | Art Unit 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-16-05; 12-8-06</u> | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1796

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 are rejected under 35

U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

Note Hirvonen et al., newly cited who disclose that experiments attempting to transfer solatol with human cadaver skin while varying sodium chloride concentration were unsuccessful in enhancing delivery and that "(I)n view of the present results, it is unlikely that the diffusion potential would be worth using as an enhancement method for transdermal drug delivery" (note the abstract as well as the paragraph bridging the columns on page 38). In view of the disclosure of Hirvonen those skilled in the art would therefore question weather agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) would cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70 and 72-77 are rejected under 35 U.S.C.

112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention. In view of the disclosure of Hirvonen, cited above, those skilled in the art would question whether agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) would cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed and applicants method in which agents for creating a hostile biophysical environment (such as are disclosed by applicants to include salts such as sodium chloride) cause the L-arginine (derivative) of the claims to migrate from the delivery vehicle to the skin (including the penis) as claimed does not appear to be enabled.

Claims 50 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 59 ultimately depend from cancelled claims and are therefore unclear.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis at telephone number 571 272 1075, M-F, 9-5pm.

Jeffrey C. Mullis
Primary Examiner
Art Unit 1796

/Jeffrey C. Mullis/

Primary Examiner, Art Unit 1796

